Office Action Summary

Application No.	Applicant(s)
09/090,754	Srivastava
Examiner	**Group Art Unit**
Geetha P. Bansal	1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 6/4/98 and 1/13/99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 60-77 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 60-77 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 62-67, 76-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides and proteins, does not reasonably provide enablement for all antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to a method of purifying hsp70 complexes comprising adding hsp associated with peptides, polypeptides, denatured proteins and antigens to an ADP matrix and eluting the bound complexes with a buffer containing ADP to collect the desired hsp70 complexes. The claims also specify that the complexes can be purified from a cell lysate and includes hsps from prokaryotic, eukaryotic and yeast cells.

The specification teaches noncovalent association of hsp-peptide or protein complexes. The art also teaches us that hsps are classically chaperones for newly synthesized proteins as well as play a role in maintaining protein stability (see references cited in PTO1449- #BS-Lindquist et al (1988) and #BC-Craig et al (1993)). There is no teaching in the specification as to what other antigens, other than peptides and proteins fall within the scope of antigens that are associated with hsps and more specifically with hsp70. The specification provides no guidance as to the nature of the antigen molecule derived from the various sources. Potentially any molecule on the surface of

a cell or present in a cell is antigenic. There is no teaching as to the identification of antigens as claimed, that can complex with the different hsps and be able to induce an immune response. An antigenic molecule could be any chemical molecule that can be recognized by components of the immune system and can also be of any size - as for e.g. a peptide of at least three aminoacids to a big protein molecule, a carbohydrate, nucleic acid, a polysaccharide etc. Further, the specification also does not provide guidance as to how to produce or identify and make complexes of hsps and any antigen and specifically those that are non-covalently bound to each other. It would be undue experimentation for one of skill in the art to practice the claimed invention because one of skill in the art cannot anticipate the particular antigenic molecule from the vast number of chemically and structurally different antigenic molecules - for e.g. it would be undue burden to select an antigenic molecule of the instant claims because one is not taught the specific structure or characteristics of the antigen. The sole working example using gp96-peptide complex from a cancer cell is not sufficient indicator that all other antigenic molecules from all the different sources will be capable of associating with the hsps and obtain the ability to induce an immune response. The specification does not provide sufficient guidance as to which antigens out of the potentially large number of antigenic moieties present on each of the individual, organism or species etc would be encompassed as complexing with heat shock proteins, and specifically there is no teaching as to the nature of the antigen. The specification discloses the isolation of gp96-peptide complex, and using it to induce an immune response to the tumor from which the complex was derived, and shown to be a CTL response. But, gp96-peptide complex is an unrelated protein to all the different antigens that are known in the art. Potentially any molecule on the surface of a cell or present in a cell is antigenic. There is no teaching as to the identification of antigens as claimed that can complex with the different hsps and be able to induce an immune response. In view of the unpredictability of the art, lack of guidance and limited working examples and the amount of experimentation required to produce the claimed antigens and fragments and derivatives thereof

commensurate in scope with the claims, it would be undue burden for one of skill in the art to practice the claimed invention by the methods described in the instant specification.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 62-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim are ambiguous in that it is not clear what the differences are between peptide, polypeptide, denatured protein and antigen are. Essentially an antigen is any one of the three others and a denatured protein is also a peptide or a polypeptide.

B. Claims 72 -73 are indefinite in that it is not clear what a synthetic hsp-peptide complex is that comprises hsp and a peptide from an individual.

5. The following references are cited as being relevant to the claimed invention.

Clarke et al, Molecular and Cellular Biology, Vol.8, No. 3, pp 1206-1215, March 1988.

Sherman et al, Journal of Bacteriology, Vol. 173, No. 22, pp 7249-7256, 1991.

6. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell, can be reached on (703) 308-4310.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 15, 1999.

GEETHA BANSAL
PATENT EXAMINER
Bansal